FDA Basics

FDA's Import Operations: How FDA Regulates Imported Products

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PRESENTATION OVERVIEW

I. General Overview of FDA and Import Law

- ✓ What we regulate
- ✓ Section 801 of FFD&CA
- ✓ “appears” and “or otherwise”
- ✓ “shall” refuse admission

II. The Import Process

- ✓ Entry Review
- ✓ Detentions
- ✓ Examinations/Samples
- ✓ Refusals

III. Drug Entry Review

- ✓ Requirements
- ✓ Reasons for Detentions & Exemptions
- ✓ Safety Issues

Products regulated by FDA

- Human foods (exceptions: most meat and poultry)
- Animal feeds
- Cosmetics
- Drugs (both human and animal)
- Biologics (including human cells and tissues)
- Medical devices
- Electronic products that emit radiation
- Tobacco

Imported products are required to meet the same standards as domestic goods

FDA and Imports

- FDA provides consumer protection by enforcing the Federal Food Drug & Cosmetic Act (FFD&CA)
- Imports are addressed in FFD&CA section 801
- 801: Allows for refusal of imported FDA-regulated products for appearing to be adulterated or misbranded based on evidence

- Adulteration: content of a product (such as the addition of a substance which makes a product inferior, impure, not genuine, etc.)

- Misbranding: statements on labels or labeling that are false or misleading

FDA Import Law
FFD&CA section 801

- FDA has jurisdiction over the products it regulates – 801 gives no new jurisdiction

- 801 provides for how FDA regulates those products at the time of entry

FDA Import Law
FFD&CA section 801

- **Section 801 of the FFD&CA**

"If it *appears* from the examination of such samples *or otherwise* that…"

(1) such article has been manufactured, processed, or packed under insanitary conditions… or

(2) such article is forbidden or restricted in sale in the country in which it was produced … or

(3) such article is adulterated, misbranded, or in violation of section 505 (New Drugs)

"then such article *shall* be refused admission…"

Food Drug & Cosmetic Act FDA

Chapter VIII – Imports and Exports

"**appears**" – provides FDA's standard of proof

- We can refuse entry to goods that:
  - Appear to be adulterated or misbranded
  - Appear to be unapproved new drugs
  - Appear to have been manufactured not in accordance with GMPs

Food Drug & Cosmetic Act FDA

Chapter VIII – Imports and Exports

"**or otherwise**" – allows FDA to make admissibility decisions using:

- Historical data
- Examinations (vs. sample collections)
- Information from other sources
- Other evidence

Food Drug & Cosmetic Act FDA

Chapter VIII – Imports and Exports

"…**shall** be refused admission…" – directs FDA's action

- The intent of the law is to deny importation of violative articles
- Articles are expected and required to be in compliance *at the time of entry*
- Compare to other sections of FDA law (seizure)

The Import Process

US Customs and Border Protection (CBP) is the initial authority for all imported products:

- ✓ Entry is made to CBP
- ✓ If FDA regulated, CBP forwards to FDA
- ✓ FDA then begins its admissibility process

The Import Process: Entry Review

Entry Reviewers

- FDA has trained individuals who review entry declarations and evaluate the admissibility of a product.

- Entry reviewers have several options:
  - Release the product
  - Request examination of the product
  - Request additional information or documents
  - Recommend detention of the product

The Import Process: Release

- Product may be distributed
- FDA still has jurisdiction
- Does not preclude FDA action if a problem is found later

The Import Process: Detention

- FDA “detention” is an administrative process
  - NOT a physical hold of the product
  - Importer has the right to take possession of the articles
- FDA can detain based upon “appearance” of a violation
  - Importer has the right to give evidence to refute this appearance
  - This is known as the “Detention and Hearing Process”
- Based on the evidence, the detention will either stand (refusal) or be overturned (release)

The Import Process: Detention

- FDA Detention Notice to importer and consignee
  - Indicates our belief the articles are subject to refusal
  - Reason(s) why
  - Right to provide testimony (evidence)
  - Timeframe for response
  - Contact name/number

The Import Process: Detention

- Importer can also petition to recondition the goods to bring them into compliance
  - Relabeling a misbranded product
  - Cleansing an adulterated product
  - Making a product not FDA regulated
- Reconditioning must be approved by FDA

The Import Process: Examinations

- Field personnel will examine for evidence of:
  - Filth
  - Decomposition
  - Packaging defects
  - Mishandling of products
  - Misbranding
- Examinations may uncover “appearance” of violations

The Import Process: Examinations

Investigators/Inspectors

- Go out to the port or destination and conduct an examination of the shipment, which may include a physical exam, label review, sample collection.
- If a sample is collected, it is packaged and shipped to the appropriate laboratory for analysis.
- The appropriate documentation is completed and data recorded in FDA's database.

The Import Process: Laboratory Analysis

Laboratory Analyst

- The laboratory receives samples from the field and perform the appropriate analyst of the sample.
- Analysts record their findings in the appropriate database.

The Import Process: Examinations/Sample Collections

- If apparent violations are discovered
  - Detention and Hearing Process begins
  - About 4 slides up
- If no violations are discovered
  - FDA Release

The Import Process: Refusal of Admission

- If a detained product can not be brought into compliance, FDA will refuse entry
- Refused product may be exported or destroyed
- Civil Money Penalties if products are not exported or destroyed
- FDA does have authority to seize product if certain criteria have been met

Import Alerts

- Historical data showing:
  - Commodities
  - Manufacturers/shippers
  - Countries of origin
  - Or combinations of the above
- Appear to be producing or shipping products that violate the FFD&CA

- http://www.accessdata.fda.gov/cms_ia/ialist.html

Import Alerts

- Provide information to the field offices
- Field can use this information to detain goods without examining them
- Keep FDA from having to sample over and over again
- Products stay on an Import Alert until the firm proves it can produce a compliant product

Protecting the Public

Fiscal Year 2011 (10/1/2010 – 9/30/2011)

- Approximately 22.7M lines of imported FDA-regulated product

Category	Total Lines	Share of Imported Lines
Human Foods	8,975,308	39.6%
Animal Foods	234,977	1.0%
Housewares and Food-Related Items	1,213,786	5.4.%
Cosmetics	2,121,084	9.4%
Drugs and Biologics	525,737	2.3%
Devices	8,766,595	38.6%
Electronics	833,516	3.7%
Tobacco Products	13,258	0.1%

Protecting the Public

- FY2011 Activities

Category	Total Lines	Exams	Sample Collections	Detentions	Refusals
Human Foods	8,975,308	244,364	27,483	41,407	10,405
Animal Foods	234,977	6,029	648	1,618	159
Housewares and Food-Related Items	1,213,786	5,898	187	154	67
Cosmetics	2,121,084	19,222	618	4,116	1,577
Drugs and Biologics	525,737	12,517	368	10,213	2,976
Devices	8,766,595	21,765	1,291	131,981	62,498
Electronics	833,516	715	80	644	174
Tobacco Products	13,258	783	1	24	3
	22,684,261	311,293	30,676	190,157	77,859

Thank you

Questions?

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